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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,969	10/15/2004	Scott R. Breining	T103 1580.1	5968
26158 7590 05/01/2007 WOMBLE CARLYLE SANDRIDGE & RICE, PLLC ATTN: PATENT DOCKETING 32ND FLOOR P.O. BOX 7037 ATLANTA, GA 30357-0037			EXAMINER O DELL, DAVID K	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/711,969

Applicant(s)

BREINING ET AL.

Examiner

David K. O'Dell, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 1-72 are pending in the current application.
2. This application claims benefit of U.S. Provisional Application 60/511,697 filed October 15, 2003.

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 8, 12, 13, 15-18 drawn to compounds where in either Formula I or Formula II of claim 1,  $k=1$ ,  $p=1$ ,  $Z_j$  is H or  $j$  is 0, Ar is 3-pyridyl, and if  $m$  is 1 then  $n$  is 0 or if  $n$  is 1  $m$  is 0, drawn to compounds and compositions having either a 2-(pyridin-3-yl)-7-azabicyclo[3.3.1]non-2-ene core **IA**, or a 3-(pyridin-3-yl)-7-azabicyclo[3.3.1]non-2-ene core **IB**, or a 2-(pyridin-3-yl)-7-azabicyclo[3.3.1]nonane core **IC** or a 3-(pyridin-3-yl)-7-azabicyclo[3.3.1]nonane core **ID** as shown in Figure 1, classified in class 540, subclass 477.
- II. Claims 1-4, 10, 12, 14-18 drawn to compounds where in either Formula I or Formula II of claim 1  $Z_j$  is H or  $j$  is 0, Ar is 3-pyridyl, limited to the following subsets of  $k$ ,  $m$ ,  $n$ , &  $p$ : subset 1: if  $k=0$  then  $p=1$ ,  $m$  is 0,  $n$  is 1, or subset 2: if  $k$  is 1, then  $p$  is 0, and  $m$  is 1 and  $n$  is 0 or  $n$  is 1 and  $m$  is 0, drawn to compounds and compositions having either a 2-(pyridin-3-yl)-7-azabicyclo[3.2.1]oct-2-ene core **IIA**, or a 3-(pyridin-3-yl)-7-azabicyclo[3.2.1]oct-2-ene core **IIB**, or a 3-(pyridin-3-yl)-6-azabicyclo[3.2.1]oct-2-ene core **IIC** or a 2-(pyridin-3-yl)-7-azabicyclo[3.2.1]octane core **IID** or a 3-(pyridin-3-yl)-7-azabicyclo[3.2.1]octane core **IIE** classified in class 540, subclass 582.

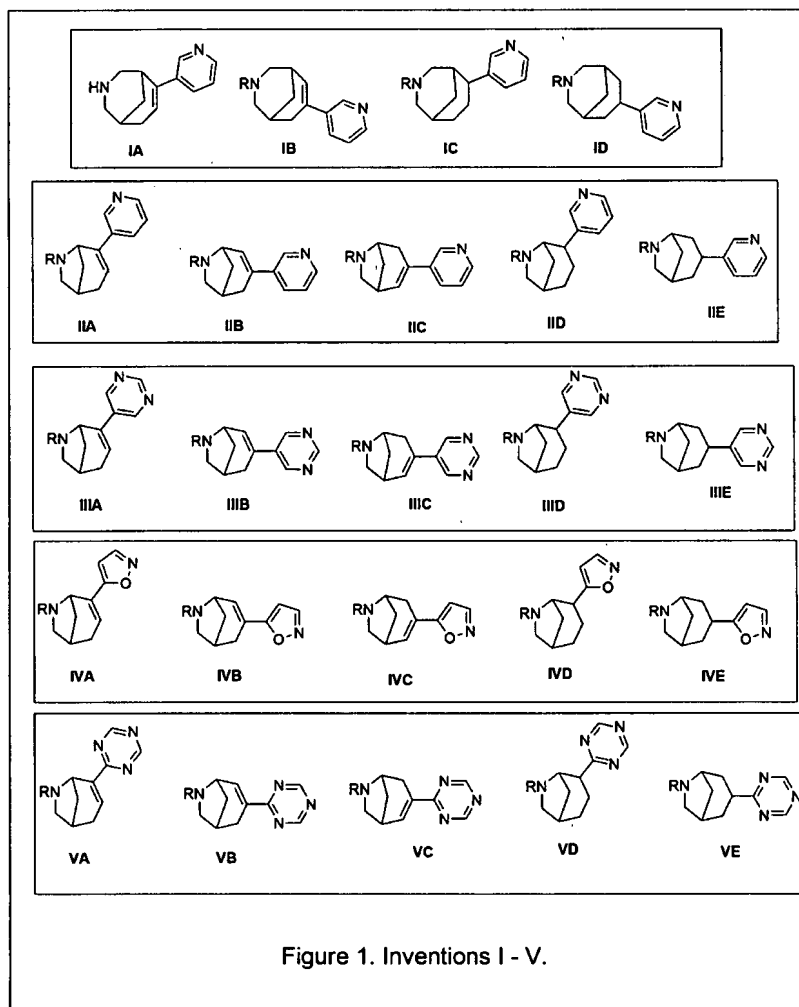
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- III. Claims 1-3, 5, 10, 12, 14-17 drawn to compounds where in either Formula I or Formula II of claim 1 Z<sub>j</sub> is H or j is 0, Ar is 3-pyrimidinyl, limited to the following subsets of k, m, n, & p: subset 1: if, k=0 then p=1, m is 0, n is 1, or subset 2: if k is 1, then p is 0, and m is 1 and n is 0 or n is 1 and m is 0, drawn to compounds and compositions having either a 2-(pyrimidin-3-yl)-7-azabicyclo[3.2.1]oct-2-ene core **IIIA**, or a 3-(pyrimidin-3-yl)-7-azabicyclo[3.2.1]oct-2-ene core **IIIB**, or a 3-(pyrimidin-3-yl)-6-azabicyclo[3.2.1]oct-2-ene core **IIIC** or a 2-(pyrimidin-3-yl)-7-azabicyclo[3.2.1]octane core **IIID** or a 3-(pyrimidin-3-yl)-7-azabicyclo[3.2.1]octane core **IIIE** classified in class 540, subclass 583.
- IV. Claims 1-3, 10, 12, 14, 15, 16 drawn to compounds where in either Formula I or Formula II of claim 1 Z<sub>j</sub> is H or j is 0, Ar is 5-isoxazole, limited to the following subsets of k, m, n, & p: subset 1: if, k=0 then p=1, m is 0, n is 1, or subset 2: if k is 1, then p is 0, and m is 1 and n is 0 or n is 1 and m is 0, drawn to compounds and compositions having either a 2-(isoxazol-5-yl)-7-azabicyclo[3.2.1]oct-2-ene core **IVA**, or a 3-(isoxazol-5-yl)-7-azabicyclo[3.2.1]oct-2-ene core **IVB**, or a 3-(isoxazol-5-yl)-6-azabicyclo[3.2.1]oct-2-ene core **IVC** or a 2-(isoxazol-5-yl)-7-azabicyclo[3.2.1]octane core **IVD** or a 3-(isoxazol-5-yl)-7-azabicyclo[3.2.1]octane core **IVE** classified in class 540, subclass 584.
- V. Claims 1-3, 6, 7, 9-12, 14-17 drawn to compounds where in either Formula I or Formula II of claim 1 Z<sub>j</sub> is H or j is 0, Ar is 2-(1,3,5-triazine), limited to the following subsets of k, m, n, & p: subset 1: if, k=0 then p=1, m is 0, n is 1, or subset 2: if k is 1, then p is 0, and m is 1 and n is 0 or n is 1 and m is 0, drawn

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to compounds and compositions having either a 2-(1,3,5-triazin-2-yl)-7-azabicyclo[3.2.1]oct-2-ene core **VA**, or a 3-(1,3,5-triazin-2-yl)-7-azabicyclo[3.2.1]oct-2-ene core **VB**, or a 3-(1,3,5-triazin-2-yl)-6-azabicyclo[3.2.1]oct-2-ene core **VC** or a 2-(1,3,5-triazin-2-yl)-7-azabicyclo[3.2.1]octane core **VD** or a 3-(1,3,5-triazin-2-yl)-7-azabicyclo[3.2.1]octane core **VE** classified in class 540, subclass 585, and others not classified here subject to further restriction.

Figure 1 has been provided to applicant to aid election.



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- VI. Claims 19-22, 26, 30, 31, 33-37 drawn to methods of treating various central nervous system disorders with the compounds of invention I, classified in class 514 subclass 903 and various subclasses.
- VII. Claims 19-22, 28, 30, 32-37 drawn to methods of treating various central nervous system disorders with the compounds of invention II, classified in class 514 subclass 903 and various subclasses.
- VIII. Claims 19-21, 23, 28, 30, 32-35, 37 drawn to methods of treating various central nervous system disorders with the compounds of invention III, classified in class 514 subclass 903 and various subclasses.
- IX. Claims 19-21, 28, 30, 32-34, 37 drawn to methods of treating various central nervous system disorders with the compounds of invention IV, classified in class 514 subclass 903 and various subclasses.
- X. Claims 19-21, 24-25, 27-30, 32-35, 37 drawn to methods of treating various central nervous system disorders with the compounds of invention V, classified in class 514 subclass 903 and various subclasses.
- XI. Claims 38-43, 47, 51, 52, 54-57 drawn to methods of treating pain with the compounds of invention I, classified in class 514, subclass 817 and various subclasses.
- XII. Claims 38-43, 49, 51, 53-57 drawn to methods of treating pain with the compounds of invention II, classified in class 514, subclass 817 and various subclasses.

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- XIII. Claims 38-42, 44, 49, 51, 53-56 drawn to methods of treating pain with the compounds of invention III, classified in class 514, subclass 817 and various subclasses.
- XIV. Claims 38-42, 49, 51, 53-55 drawn to methods of treating pain with the compounds of invention IV, classified in class 514, subclass 817 and various subclasses.
- XV. Claims 38-42, 45, 46, 48-51, 53-56 drawn to methods of treating pain with the compounds of invention V, classified in class 514, subclass 817 and various subclasses.
- XVI. to XX. Claims 58-62 drawn to methods of treating inflammation with compounds classified in class 514 subclass 886 and various subclasses limited in scope to a single invention I-V.
- XXI. to XXV. Claims 63-68 drawn to methods of treating cancer with compounds classified in class 514 subclass 908 and various subclasses limited in scope to a single invention I-V.
- XXVI. to XXX. Claims 63-68 drawn to methods of treating ischemia with compounds classified in class 514 subclass 929 and various subclasses limited in scope to a single invention I-V.
- XXXI. to XXXV. Claim 72 drawn to methods of treating drug addiction etc. with compounds classified in class 514 subclass 810 and various subclasses limited in scope to a single invention I-V.
- XXXVI. to XXXX. Claim 71 drawn to methods of treating abnormal cytokine levels with

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compounds classified in class 514 subclass 885 and various subclasses limited in scope to a single invention I-V.

XXXXI. to XXXXVI. Claim 70 drawn to compositions of known drugs with the compounds of the instant case classified in class 514 subclass 823 and various subclasses limited in scope to a single invention I-V.

The inventions are independent and distinct for the following reasons:

3. Inventions I - V are directed to chemical compounds related in their claimed method of use. The compounds are distinct because the inventions as claimed have a materially different structure, and the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in I - V are chemical compounds which do not share substantial structural features recognized in the art as being essential to the disclosed utility (hence their different classification). A search for one invention would necessarily be mutually exclusive to the search of the other inventions; hence the insuperable search burden would preclude examination. A reference that anticipates any one of the inventions I - V would not render the other groups obvious. Should applicant traverse on the grounds that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now showing that inventions I - V are obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable



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over the prior art, the evidence or admission may be used in an obviousness rejection under 35 U.S.C. § 103 (a).

4. Inventions I - V are related to Inventions VI-X, XI-XV, XVI-XX, XXI-XXV, XXVI-XXX, XXXI-XXXV, XXXVI-XXXX and XXXXI-XXXXV paired respectively in pentets (i.e. I:VI, II:VII.....I:XI, II:XII...), as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process can be practiced with a materially different product. For example, aspirin may be used to treat pain, alcohol abuse may be treated with antabuse, CNS disorders may be treated with psychotherapy, inflammation may be treated with ibuprofen or other NSAIDS, cancer may be treated with radiation, and abnormal cytokine levels may be treated with quotidian nocturnal hemodialysis (Yuen, Darren; Richardson, Robert M. A.; Fenton, Stanley S. A.; McGrath-Chong, Margaret E.; Chan, Christopher T. "Quotidian Nocturnal Hemodialysis Improves Cytokine Profile and Enhances Erythropoietin Responsiveness." ASAIO Journal. 51(3):236-241, May/June 2005. Abstract only)

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. Because these inventions are independent or distinct for the reasons given above and there would be a serious

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burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.041. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*; *In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the

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right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). **If Invention V or processes drawn to the use of said invention is elected**, the applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that if Inventions V or processes drawn to the use of said inventions are elected a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §

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809.02(a). **This requirement is not required for Inventions I-IV** or processes drawn the use of said inventions.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell, Ph.D. whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Cecilia Tsang can be reached at (571)-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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D.K.O.

**VICKIE KIM**  
**PRIMARY EXAMINER**

A large, stylized handwritten signature in black ink, consisting of several loops and a long horizontal stroke, is written over the printed name and title.